# 510（K）Summary of Safety and Effectiveness

FEB 25 2014

This summary of 510k safety and effectiveness is being submitted in according with 21CFR part 807.92
The 510(k) number is (if known)_____

**Submitter:**

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**Contact person:**

Cherry Sun
Edan Instruments, Inc.

**Proprietary Name:**

SE-601 Series Electrocardiograph

**Classification information:**

21 CFR 870.2340, Electrocardiograph
Class II

**Product code:**

DPS

**Review Panel:**

Cardiovascular

**Predicate Devices:**

PC ECG cleared under K092010
Manufacturer: Edan Instruments, Inc.
SE-601 series Electrocardiograph cleared under K093869
Manufacturer: Edan Instruments, Inc.

**Device Description:**

SE-601 series Smart ECG includes three models SE-601A, SE-601B and SE-601C.
Device features include as follows:

- Portable, lightweight design
- Easy data input and operation
- Alphanumeric keyboard and one-touch operation
- Built-in rechargeable battery, AC/DC power supply
- Automatic analysis and diagnostic software (SEMIP) for adults and pediatrics
- Two-step exercise test with periodic recording
- Heart rate variability (HRV) analysis

- Internal thermal printer and external printer
- Support external archiving: USB flash disk, card reader
- Data transmission to PC via Ethernet , WIFI or serial port

**Intended Use:**

This submission is to modify the indication for use (intended use) by adding the applicable pediatric population.

The intended use of SE-601 is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is only intended to be used on adult patients and is offered to clinicians on an advisory basis only.

**Test Summary:**

The following quality assurance measures were applied to the development of the SE-601 Series Electrocardiograph:

- Software testing
- Risk analysis
- Safety testing
- Performance testing
- Environmental testing

**Conclusion:**

Verification and validation testing was done on SE-601 Series Electrocardiograph. This premarket notification submission demonstrates that the subject device SE-601 Series Electrocardiograph is substantially equivalent to the predicate device above mentioned

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 25, 2014

Edan Instruments, Inc.
Ms. Cherry Sun
Certification Engineer
Nanhai Road 1019# Nanshen
Shenzhen, Guangdong, China 518067

Re: K131503
Trade/Device Name: SE-601 Series Electrocardiograph
Regulation Number: 21 CFR 870.2340
Regulation Name: Electrocardiograph
Regulatory Class: Class II
Product Code: DPS
Dated: January 21, 2014
Received: January 28, 2014

Dear Ms. Cherry Sun:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

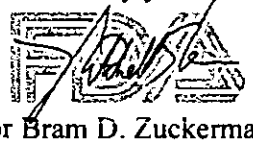
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indication for Use

510(k) Number:

Device Name: SE-601 Series Electrocardiograph

The intended use of SE-601 is to acquire ECG signals from adult and pediatric patients through body surface ECG electrodes. The electrocardiograph is only intended to be used in hospitals or healthcare facilities by doctors and trained healthcare professionals. The cardiogram recorded by the electrocardiograph can help users to analyze and diagnose heart disease. However, the interpreted ECG with measurements and interpretive statements is only intended to be used on adult patients and is offered to clinicians on an advisory basis only.

Prescription Use ___X___ Or Over the Counter Use _____

(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Concur for B. Zuckerman

Date: 2014.02.25 13:39:48 -05'00'